USSN# 09/821,103 CASE TN17-NP

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Warren K. Volles		November 3, 2003
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

ABRAMOWITZ ET AL.

APPLICATION NO: 09/821,103

FILED: MARCH 29, 2001

FOR: SUSTAINED RELEASE BEADLETS CONTAINING STAVUDINE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

In the Office Action dated October 3, 2003, restriction to one of the following groups was required:

I. Claims 1-25 drawn to beadlets comprising stavudine, classified in class 514, subclass 50.
II. Claims 26-30 drawn to a method for treating a retroviral infection with stavudine and optionally with an additional anti-retroviral agent, classified in class 514, subclass 46+.
III. Claims 31-34 drawn to a process for preparing a stavudine composition classified in class 424, subclass 489+.

As stated on page 2 of the Office Action, the Examiner's position is:

> The Inventions are distinct, each from the other because of the following reasons:
>
> 1. Groups I and II are related as product and process for using, wherein any number of alternative anti-r troviral agents can be set forth as seen in the patent literature.

2. Group I, II and III are related as process of making and product made. The inventions are distinct if either or both of the following an be shown: (1) that the process as claimed can be used to make oth r and materially diff rent product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process of U.S. Patent 6,486,136 could be used to make a controlled release composition for use to treat a retroviral infection.
3. Groups II and III are related as unrelated methods. The manner in which the composition to be used in the method of Group III is made is not seen to be of patentable import. The record does not indicate that these methods must be practiced together, and the modes of operation, one is synthetic mode of operation and the other is a chemotherapeutic mode of action. Group III functions to produce a product, while Group II functions to provide a therapeutic effect.

With respect to Groups I and II it is respectfully submitted that the alternative use suggested by the Examiner cannot be accomplished. In particular, the claims of Group I recite that the extruded-spheronized beadlets comprise stavudine (e.g. Claims 1, 15 and 19) and the claims of Group II specificially refer to the beadlets of claims 1, 15 or 19 to provide an effective dosage of stavudine. Thus, all of the claims of Groups I and II are specifically directed to the anti-retroviral agent stavudine.

With respect to Groups I, II and III it is respectfully submitted that the Examiner has failed to show that the process of U.S. Patent 6,486,136 can be used to make extruded beadlets containing stavudine which contain an amount of magnesium stearate sufficient to stabilize the stavudine against degradation, i.e., conversion to thymine, during the process.

For the forgoing reasons it is respectfully submitted that the U.S. Patent and Trademark Office has failed to meet its burden to support the restriction requirement. Hence, the restriction requirement is traversed.

Notwithstanding the traverse, applicants provisionally elect the invention of Group I claims 1 to 25.

With respect to the species election, applicants note that the four species set out by the Examiner are set forth in dependent claims 23 and 28. Dependent claim 23 is dependent from claim 22 (dependent from claim 21) which relates to a pharmaceutical dosage form containing stavudine. Dependent claim 28 is dependent from independent claim 26 which is related to a method for treating a patient comprising the administration of an effective dosage of stavudine. Thus, the species set out by the Examiner are other medicaments useful in treating retroviral

infections in addition to stavudin . Once the invention is examined with respect t stavudine, it is applicants' position that the further examination of the other medicaments would not be unduly burdensome to the Patent Office. Accordingly, reconsideration of the species election requirement is r spectfully requested. Notwithstanding the traverse, applicants pr visionally elect species I didanosine for examination purposes.

An early and favorable Office Action is courteously solicited.

Respectfully submitted,

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